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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,639

Applicant(s)

NALDINI ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-30 and 33-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30 and 33-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-27, 30, 33-37 and 41-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnston et al.

Applicants claim a lentiviral vector system comprising a lentiviral packaging system and a lentiviral transfer vector comprising a heterologous gene operably linked to a regulatory element, wherein the lentiviral packaging system comprises a structural lentiviral vector system comprising a first lentiviral vector that encodes a structural gene (operably linked to a heterologous promoter, i.e. CMV promoter) selected from a gag gene, a pol gene or both gag and pol genes and a RRE downstream of the structural gene(s); and a regulatory lentiviral vector comprising a rev gene operably linked to a heterologous promoter which can comprise RSV U3 or HSVtk promoter), wherein the regulatory lentiviral vector is provided on a separate construct from the structural lentiviral vector system, wherein the lentiviral transfer vector comprises a 5' LTR and a 3' LTR, each of which contains a U3 region, wherein the regulatory element is a heterologous regulatory element operable in a mammalian cell, wherein a part or all of a regulatory element of the U3 region of the 5' LTR is replaced by the heterologous

regulatory element, and wherein a part or all of the U3 region of the 3' LTR is replaced by a heterologous inducible regulatory element (which can comprise a tet operator) that is activated only in the presence of an activator expressed in trans, a further vector construct comprising a heterologous env gene wherein the env gene is not from HIV and the lentiviral vector system does not have vif, vpr, vpu and nef genes and a method of producing a recombinant lentivirus comprising transfecting a packaging host cell with the lentiviral vector system and recovering recombinant lentivirus produced by the cell.

Johnston et al. (US 20030104611, published 6/5/2003, see whole document, particularly Figs. 3-4, paragraphs [0009], [0012]-[0016], [0042], [0045]-[0049], [0054], [0056], [0061], [0065], [0116], [0401]-[0409], [0435], [0448]-[0453]) recites a lentiviral (FIV) vector system comprising a lentiviral packaging system and a lentiviral transfer vector comprising a heterologous gene operably linked to a regulatory element, wherein the lentiviral packaging system comprises a structural lentiviral vector system comprising a first lentiviral vector that encodes a structural gene (operably linked to a heterologous promoter, i.e. CMV promoter) selected from a gag gene, a pol gene or both gag and pol genes and a RRE downstream of the structural gene(s); and a separate lentiviral vector comprising a rev gene operably linked to a heterologous promoter (Johnston et al. recites that the heterologous promoter used to drive expression of any of the lentiviral genes can be the RSV promoter (which comprises the U3 region) or HSVtk promoter, wherein the lentiviral transfer vector can be a self-inactivating vector (SIN vector) which comprises a 5' LTR and a 3' LTR, each of which contains a U3 region, wherein the regulatory element is a heterologous regulatory

Art Unit: 1636

element operable in a mammalian cell, wherein a part or all of a regulatory element of the U3 region of the 5' LTR is replaced by the heterologous regulatory element, and wherein a part or all of the U3 region of the 3' LTR is replaced by a heterologous inducible regulatory element (which can comprise a tet operator) that is activated only in the presence of an activator expressed in trans, a further vector construct comprising a heterologous env gene wherein the env gene is not from HIV and the lentiviral vector system does not have vif, vpr, vpu and nef genes (it is noted that the FIV vectors recited by Johnston et al. do not have nef, vpr or vpu genes and can be deleted of the vif gene) and a method of producing a recombinant lentivirus comprising transfecting a packaging host cell with the lentiviral vector system and recovering recombinant lentivirus produced by the cell. Johnston et al. therefore teaches the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. in view of Bujard et al.

Applicants' invention is as described in the above 35 USC 102(e) rejection. In addition, applicants recite that the heterologous inducible regulatory element comprises seven copies of a tet operator (tet^o7).

Johnston et al. is applied as in the above 35 USC 102(e) rejection. Johnston et al. recites use of the tet inducible promoter system but does not recite that the heterologous inducible regulatory element comprises seven copies of a tet operator (tet^o7).

Bujard et al. (US 5,589,362, issued 12/31/1996, see whole document, particularly columns 17-18) recites the tet inducible promoter system wherein a preferred embodiment includes operably linking the sequence to be transcribed to seven tet operator sequences.

The ordinary skilled artisan, seeking to use the well known tet inducible promoter system (as recited by Johnston et al.) would have been motivated to operably link the sequence to be transcribed to seven tet operator sequences because Bujard et al. specifically recites that a preferred embodiment of the tet inducible system involves operably linking seven tet operator sequences to the sequence to be transcribed. It would have been obvious for the ordinary skilled artisan to operably link seven tet operator sequences to the sequence of interest to be transcribed because Johnston et

Art Unit: 1636

al. recites that the tet inducible promoter system can be used to express genes of interest in the lentiviral vectors and Bujard et al. teaches that a preferred embodiment of the tet inducible promoter system involves operably linking seven copies of the tet operator to the sequence to be transcribed. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-30 and 33-46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 (and dependent claims) are vague in that claim 26 recites that the lentiviral transfer vector "comprises a 5' LTR and a 3' LTR, **each of which contains a U3 region** (emphasis added)" and later in the claim recites that part or all of the **U3 regions in the 3' and 5'; LTRs are replaced by heterologous regulatory elements.**

The claim is therefore contradictory in that it recites that the 3' and 5' LTRs of the transfer vector each contain a U3 region and then recites that the entire U3 region is replaced by a heterologous regulatory element. The vector cannot simultaneously possess a U3 region and lack the same U3 region.

Art Unit: 1636

No Claims are allowed.

Any rejections not repeated in this Office Action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
September 19, 2006


DAVID GUZO
PRIMARY EXAMINER